

Remarks

This Amendment is in response to the Office Action dated **July 30, 2008**.

Specification

The disclosure was objected to because of several informalities. Namely, references to attorney docket numbers on page 7, 8, 13, 17, 18 and 19. Applicants have amended the specification. No new matter has been added.

Rejections

35 U.S.C. §102(e)

Claims 1-4, 6-9, 11, 12, and 17 have been rejected under 35 U.S.C. §102(e) as being anticipated by Zamore (U.S. Patent Application No. 2004/0093008).

Claim 1 of the present application is directed to a dilatation balloon having waist portions, cone portions and a body portion. The balloon is formed of a first polymeric composition forming a first layer. The balloon has a second layer formed on at least a portion of the first layer that is crosslinked. Claim 1 has been amended to recite that the second crosslinked layer is on the waist portions, the cone portions or both, and the body portion is uncrosslinked.

These limitations are found in canceled claims 2-4. Support can also be found at least from FIG. 7, and from the description on page 20, lines 16-25. No new matter has been added.

It is asserted in the Office Action that:

Zamore discloses a dilatation balloon with waist portions, cone portions, and a

body portion where the balloon is formed of a first polymeric composition forming a first layer (A) and a second layer (B) is formed on at least a portion of the first layer. The second layer comprises a second polymeric composition which is crosslinked to form a compression region on at least a portion of the balloon Zamore discloses that the second polymeric composition is crosslinked on at least a portion of the waist portions, the cone portions, or both (paragraph [0300]).

Office Action, pages 2-3

Applicants disagree.

Zamore disclose “[m]edical dilatation balloons [that] comprise a polymer that has the attribute of memory, and/or is crosslinked to impart memory.” Abstract.

In the embodiment described in paragraph [0300] to which we are directed in the Office Action, the resultant balloon has “... a crosslinked outer layer B and a thermoplastic inner layer A ...” Paragraph [0300]. No where is it disclosed by Zamore that the crosslinking occurs only on the waist portions and/or cone portions of the balloon.

This statement made by Zamore in paragraph [0300] is also consistent with the process disclosed in paragraph [0300] for making the balloon. A layer or non-crosslinked polymer is co-extruded or otherwise applied to the inner and/or outer surface of a crosslinkable polymer tube during or after the formation of the crosslinkable polymer tube and prior to (or possibly after) exposure of the tubing assembly to crosslinking energy. This would result in a tubing assembly with a non-crosslinkable layer on the inner and/or outer surface of a crosslinkable layer of tubing. When the tubing assembly is exposed to crosslinking energy, only the crosslinkable layer will crosslink, while the uncrosslinkable layer or layers will remain uncrosslinked. “The entire co-extruded tubing comprising crosslinkable layer B and non crosslinkable layer A, is then exposed to crosslinking energy. Only the portion of the tubing consisting of outer layer B will crosslink while the inner portion of the tubing consisting of layer A will remain uncrosslinked. Since Layer A remains uncrosslinked and therefore a thermoplastic, it

will be weldable to another thermoplastic.” See paragraph [0300].

Layer B is cocxtensive with layer A. See FIG. 1B.

Nowhere does Zamore disclose only a portion of the crosslinkable layer is crosslinked, and because the entire layer is crosslinkable and the entire layer is exposed to crosslinking radiation, the entire layer will crosslink.

Claim 1 as amended is not anticipated by Zamore because Zamore fails to disclose all of the elements recited in claim 1 as required by 35 U.S.C. §102. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” (*Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Namely, Zamore fails to disclose a balloon wherein the crosslinked layer is only on the waist and/or cone portions but not on the body portion.

Claims 2-4, 6-9, 11 and 12 depend from claim 1 and are not anticipated by Zamore for at least the reasons that claim 1 is not anticipated by Zamore.

Independent claim 17 is directed to an embodiment of a dilatation balloon including, among other features, a second layer on at least one of said first and second cone portions of said balloon formed from a second composition which is crosslinked to form a compression region.

Claim 17 is not anticipated for at least the reasons that claim 1 is not anticipated by Zamore.

Applicants respectfully request withdrawal of the rejection of claims 1-4, 6-9, 11, 12, and 17 under 35 U.S.C. §102(e) as being anticipated by Zamore (U.S. Patent Application No. 2004/0093008).

35 U.S.C. §103(a)

Claims 1-9, 11-13, and 17 are rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al. (U.S. Patent No. 5,344,400) in view of Zamore (U.S. Patent Application No. 2004/0093008). It is asserted in the Office Action that:

Kaneko et al disclose the balloon substantially as claimed. Even though Kaneko et al. disclose the second layer being formed on at least a portion of the first layer and the second composition being selected from the group of olefins or comprising polyethylene (lines 47-53 of column 6), Kaneko et al. are silent on the specifics of the second polymeric composition being crosslinked to form a compression region. Zamore discloses a dilatation balloon with a first layer and a second layer on at least a portion of the first layer where the second polymeric composition is crosslinked. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the second layer of Kaneko et al. from a polymeric composition which is crosslinkable as taught by Zamore as both Kaneko et al and Zamore teach dilatation balloons with multiple layers and Zamore teaches that it is well known to provide a crosslinkable second layer in order to form balloons with varying degrees of compliancy so that the balloons can be manufactured with compliance characteristics varying from high compliance to low compliance while still having the desired burst strength.

Office Action, section no. 6, pp. 4-5

Claim 1 has been amended as discussed above and is directed to an embodiment wherein the balloon has, among other features, a second crosslinked layer that is on the waist portions, the cone portions or both, and the body portion is uncrosslinked.

Claim 17 has also been discussed above and is directed to an embodiment of a dilatation balloon including, among other features, a second layer on at least one of said first and second cone portions of said balloon formed from a second composition which is crosslinked to form a compression region.

Applicants disagree with the rejection. Independent claim 1 as amended and independent claim 17 are not obvious over Kaneko et al. in view of Zamore.

It is asserted in the Office Action, "...Kaneko et al disclose a dilatation balloon

with waist portions (10, 12), cone portions, and a body portion where the balloon is formed of a first polymeric composition forming a first layer (18) and a second layer (16) is formed on at least a portion of the first layer of the balloon ... Kaneko et al. are silent on the specifics of the second polymeric composition being crosslinked to form a compression region.”

The first statement is incorrect. Kaneko et al. in fact fail to disclose that the second layer is formed on only a portion of the first layer. Kaneko et al. in fact only disclose that the layers 16, 17 and 18 of the multilayer construction are coextensive with one another. See FIG. 3 and the corresponding description thereof at col. 6, lines 54-68 and col. 7, lines 1-2. Nowhere do Kaneko et al. suggest that any layer be applied to only a portion of the adjacent layer. None of the Kaneko et al. layers are crosslinked.

As discussed above, in contrast to the assertion in the Office Action, Zamore also fails to disclose that any layer is applied to only a portion of another layer, and that only a portion of the crosslinkable layer is crosslinked. The crosslinkable layer B disclosed by Zamore is coextensive with noncrosslinked layer A (see FIG. 1B), and the entire assembly is exposed to crosslinking energy. Consequently, the entire layer B is crosslinked. Nowhere do Zamore disclose that only a portion of layer B is crosslinked.

Therefore, the combination of references fails to disclose or suggest each and every element as recited in claims 1 or 17 because the combination fails to disclose or suggest a balloon having a second crosslinkable layer on only the waist and/or cone portions of the balloon and not on the body portion and no *prima facie* obviousness has been established. *Prima facie* obviousness under 35 U.S.C. §103(a) requires that the reference teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re*

Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2143.

Furthermore, even if the references did produce any partial layer (they do not), they would still lack the specific disclosure or suggestion to crosslink only a portion of the layer over the waist and/or cones to form a compression region for the purpose of compressing a balloon on a shaft during welding or to improve the tracking, cross and recross, and rewrap characteristics of the balloon. See page 4, lines 9-22. This specific teaching or suggestion is found only in Applicants' disclosure. Rejections based on 35 U.S.C. §103, must be made without the benefit of Applicants' invention. Hindsight reconstruction is impermissible. "However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." MPEP 2142.

Claims 1 and 17 are not obvious over Kaneko et al. in view of Zamore. Claims 2-9 and 11-13 depend from claim 1 and are not obvious over this combination for at least the reasons that claim 1 is not obvious over this combination.

Applicants respectfully request withdrawal of the rejection of claims 1-9, 11-13, and 17 under 35 U.S.C. §103(a) as being obvious over Kaneko et al. (U.S. Patent No. 5,344,400) in view of Zamore (U.S. Patent Application No. 2004/0093008).

CONCLUSION

Claims 1 and 5-17 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution.

Respectfully submitted,

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